EXHIBIT 58

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Convection warmers—a possible source of contamination in laminar airflow operating theatres?

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Summary: This work results from concerns that forced-air convection heaters applied to patients in the operating theatre might interfere with ultra-clean ventilation system and thus be a potential source of wound contamination. Air samples were taken in the operative field and the bacterial load calculated by estimating the number of colony forming units per cubic metre of air (cfu/m^3). Six tests were carried out, two in empty theatres and four during standard orthopaedic operating lists. Differences were seen between empty theatres and those standing empty for short periods during busy operating lists. Increases were seen on entry to theatre of staff and patients with the convection heaters off. A further small rise was seen after the convection heaters were turned on when applied to patients. This study showed that use of warm air convection heaters on patients produced a small increase in the number of colony forming units in ultra-clean air theatres but the levels were unlikely to have clinical significance. By far the greatest effect on numbers was movement and presence of the patient and theatre staff in the theatre.

Keywords: Convection heaters; operating theatre; ultra-clean air; infection.

Introduction

Laminar airflow or ultra-clean ventilation systems were introduced in the 1960s and are now a common feature of operating theatres. Their function is to decrease the bacterial load in the theatre,[1,2] with the aim of reducing the incidence of surgical wound infection.[3] Forced-air convection warmers, used regularly in operating theatres, have revolutionized the management of patient hypothermia during operation, with a secondary reduction in the incidence of postoperative wound infection.[4] These devices (which are often located on the floor) are used in conjunction with a specialized blanket with perforations on the underside applied to the patient. Theatre air is passed through a microbial filter, heated, and blown through a detachable hose. We set out to determine whether forced-air convection warmers might interfere with the principle of ultra-clean ventilation systems by increasing the number of particles in the operative ultra-clean area and hence the potential for infection.

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Methods and materials

Two orthopaedic operating theatres (one elective and one emergency theatre) were chosen as the site of the experiments. Both had ultra-clean cone of air ventilation systems (Howarth Ex flow 90) in place. The quality of the air is routinely tested on a regular bases

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to ensure it meets with the Health Technical Memorandum 2025 recommendations. Six separate tests were carried out: two tests were performed in the empty theatres, and four during standard orthopaedic operations (three hip replacements and one shoulder operation) with an identical full staff complement. A Casella slit sampler (Casella Co Ltd, London, England) was placed close to the middle of the operating table, inside the square canopy wall and 1 m off the floor, for air sampling at a rate of 0.7 m^3/min for 2 min. The blood agar plates (Columbia agar with horse blood, Oxoid) from the sampler were incubated at 37°C for 48 h. All samples were taken after the airflow had been running for at least 1 h. In each test the specialized perforated blanket was applied to the patient as recommended by the manufacturer. In the empty theatres the blanket was applied to the operative table. The operation of the slit samples was in the theatre only to switch it on and off.

Samples

The following air samples were taken:

Control
Theatre completely empty before the start the operation. In the 'empty theatre' tests the theatre had no preceding operations or theatre staff present. For the tests where patients were present, theatre staff had been entering the theatre as part of the routine operating list.

Pre-warmer
Patients/table in the operating zone of the airflow system with the forced-air convection warmer applied but switched off. Patients draped for operation.

Warmer on
Fifteen minutes after the warmer was switched on.

Direct
One sample was taken directly from the air blower by connecting the hose to the air-sampling device.

Bacterial counts
Bacterial counts were calculated for each sample (cfu/m^3).

Table 1 *Results of air sampling in colony forming units per cubi meter (cfu/m^3)*

Samples	Empty theatre	Warm system off	Warm system on
No patient (1)	0.00	1.25	0.00
No patient (2)	0.00	0.89	0.18
Mean	0.00	1.07	0.09
Patient (1)	2.1	1.4	3.6
Patient (2)	0.9	0.42	1.23
Patient (3)	2.0	4.6	5.9
Patient (4)	1.5	2.1	2.9
Mean	1.625	2.13	3.15

Statistics

Results were compared using the Mann–Whitney U-test.

Results

The results of the six tests are shown in Table I. Direct sampling from the air blower grew 0.53 cfu/m^3

As the number of tests was small in this pilot study, limited statistical analysis was carried out in the patient group.

No patient tests showed a rise in colony forming units with the warming system off, followed by a fall with the system on.

Patient tests showed a nonsignificant rise in the number of colony forming units between the empty theatre and warmer off ($P = 0.88$) with a further rise in number of colony forming units between warmer off and warmer on ($P = 0.48$).

There was a difference between control samples and warmer on in the empty theatre and patient tests, but numbers were too small to enable statistical assessment of significance.

Discussion

An ultra-clean ventilation system reduces the number of bacteria in the theatre air,[1,2] with the aim of reducing the incidence of surgical wound infection.[3] In laminar airflow theatres, airflow is produced in either a vertical or horizontal direction and they are equipped with high-efficiency particulate air (HEPA) filters. The cone of air ventilation systems used in this study supply an ultra-clean zone with high air velocity from the ceiling to the level of the operating table (operating zone). The surrounding area with a slower air velocity is referred to as the clean zone. The periphery of the operating theatre toward the air outlets is known as the semi-clean

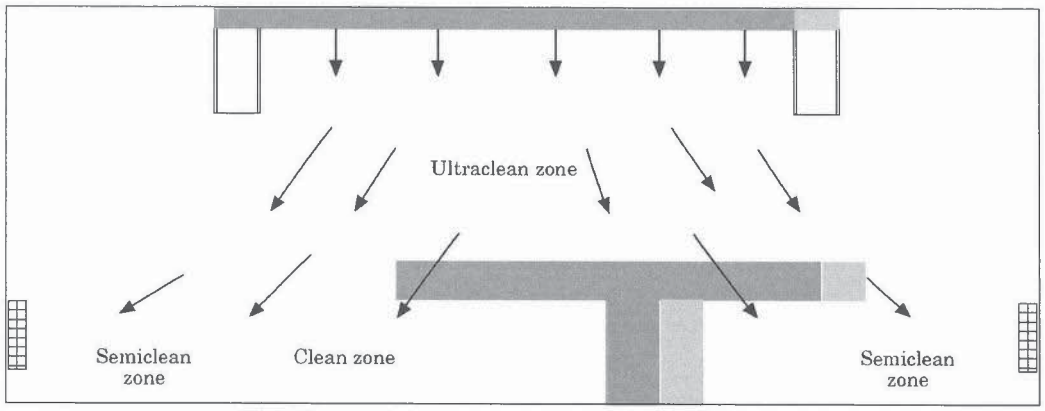

Figure 1 Zones in the ultra-clean cone of air ventillation system in operating theatres.

zone. Different air velocities result in airflow from the ultra-clean towards the clean and semi-clean zones (Figure 1).[5]

In our theatre, the heater air blower units are situated on the floor (clean zone), therefore, the airflow is reversed upwards into the ultra-clean zone. The main concerns leading to this study were, therefore, that normal airflow would be disrupted and organisms would be shed from the patients' skin due to the warm airflow over it.

In our study, a negligible number of colony forming units were grown directly from the air blower (0.53 cfu/m^3). Avidan *et al.*[6] grew pathogenic organisms directly from the airstream of warming systems, which they concluded could be a source of hospital-acquired infection. However, they showed when warming systems were used in conjunction with a perforated blanket, had the microbial filter changed regularly and the hoses sterilized, the potential for contamination was reduced.

The differences we found between the control values of in-use theatre and empty theatre groups are likely to be due to the movement of the theatre staff. In the in-use theatre tests there had been prior staff movement because of the busy operating list, whilst the empty theatre tests were performed in a theatre that had been empty for some time.

The rise in counts seen in both groups, between control and warmer off-values, is likely to be explained by the disturbance of airflow created by staff movement, patient entry into theatre and the application of the blanket to both patient and table; the differences in the two will be related to the number of personnel in theatre.

In the empty theatre tests, counts fell between warmer off and warmer on as the disturbance to airflow created by application of the blanket to the table was negated by the airflow system. Counts also confirmed the negligible number of colony forming units arising from the blower itself.

In the patient tests, counts were slightly higher with the warmer on, indicating that the warmer itself might produce a slight increase in the bacterial load. However, at no time did the average number of bacteria approach the maximum recommended (of 10 cfu/m^3) for the ultra-clean air theatres.[7] This rise, therefore, is unlikely to be clinically significant, and the benefits of patient normothermia would appear to outweigh the theoretical disadvantages of warm air heaters in ultra-clean air theatres.

This study showed that use of warm air convection heaters on patients produced a small increase in the number of colony forming units in ultra-clean air theatres but the levels were unlikely to have clinical significance. By far the greatest effect on the number of colony forming units appeared to be the movement and presence of the patient and theatre staff in the theatre.

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